

Laurimed LLC

Traditional 510(k) Notification  
PolypVac Microdebrider

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**510(k) Summary**

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**A. Name, Address, Phone and Fax Number of Applicant**

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**B. Contact Person**

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**C. Date Prepared**

September 27, 2013

**D. Device Name**

Trade Name:	Laurimed PolypVac Microdebrider
Common Name:	Microdebrider
Classification Name:	Ear, nose, and throat electric or pneumatic drill

**E. Device Classification**

Classification:	21 CFR §874.4250
Product Code:	ERL
Device Class:	Class II

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**F. Predicate Devices**

The Laurimed PolypVac Microdebrider is substantially equivalent to the Medtronic Xomed, Inc., XPS 3000 System (K041413).

**G. Device Description**

The Laurimed PolypVac Microdebrider is intended for cutting and aspirating polyp tissue during sinus and nasal procedures. The system consists of a hand-held cutting device and device cleaner.

The PolypVac Microdebrider is supplied sterile and is single-use and disposable.

**H. Intended Use**

Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.

**I. Technological Comparison**

The Laurimed PolypVac Microdebrider has similar features as compared to the predicate devices in the table below.

Manufacturer	Medtronic Xomed, Inc.	Laurimed LLC
Model Name	XPS 3000 System (with RAD12 & RAD40 shaver blades)	PolypVac Microdebrider
510(k) Number	K041413	TBD
Indications for Use	Intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.  Sinus Indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/specnoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, trans-sphenoidal procedures, maxillary sinus polypectomy, circumferential maxillary antrostomy, choanal atresia, sphenoidotomy, and medial, lateral, and posterior frontal sinusotomy	Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.
Product Code	ERL	Same

<b>Manufacturer</b>	<b>Medtronic Xomed, Inc.</b>	<b>Laurimed LLC</b>
<b>Model Name</b>	<b>XPS 3000 System (with RAD12 &amp; RAD40 shaver blades)</b>	<b>PolypVac Microdebrider</b>
<b>510(k) Number</b>	<b>K041413</b>	<b>TBD</b>
<b>Mechanics of Action</b>	Cutting elements moving inside an open window with suction	Same
<b>Anatomical sites</b>	Head, neck, ear, nose (including the sinuses), and throat	Nose (including sinuses)
<b>Design Features</b>	3.5 mm Shaver Blade <ul style="list-style-type: none"> <li>• Rounded tip</li> <li>• Side-facing cutting window with serrated edges</li> <li>• Fixed curves</li> <li>• Rotatable</li> </ul> Hand-piece <ul style="list-style-type: none"> <li>• Houses electrical motor</li> <li>• Foot-switch activated</li> <li>• Proximal end attaches to user-supplied vacuum and irrigant sources</li> </ul> Console <ul style="list-style-type: none"> <li>• Electrical power source</li> </ul>	3.5 mm Shaver Blade <ul style="list-style-type: none"> <li>• Rounded tip</li> <li>• Side-facing cutting window with serrated edge</li> <li>• Malleable</li> <li>• Rotatable</li> </ul> Hand-piece <ul style="list-style-type: none"> <li>• Houses power mechanism</li> <li>• Trigger activated</li> <li>• Proximal end attaches to user-supplied vacuum and irrigant sources</li> </ul>
<b>Mechanism of Action</b>	User-supplied vacuum pump draws polyp tissue into side-facing cutting window, tissue incised by blade	User-supplied vacuum pump draws polyp tissue into side-facing cutting window, tissue incised by blade
<b>Components</b>	Hand-piece Removable Distal Shaft with Cutting Element Device Cleaner Console & Footswitch	Hand-piece with Integrated Distal Shaft with Cutting Element Device Cleaner
<b>Safety Features</b>	Blunt Tip, Side-Cutting Window, Activation switch	Same, with the addition of a low-speed motor
<b>Sterile Packaging</b>	Tyvek/Mylar Pouch for sterile / disposable distal shafts	Same
<b>Sterilization Method</b>	Ethylene Oxide (EtO) for sterile / disposable distal shafts	E-beam radiation
<b>External Device Compatibility</b>	Endoscope Vacuum pump Sterile Irrigant bag Collection Canister	Endoscope Vacuum pump Sterile Irrigant syringe or bag
<b>Biocompatible for Intended Use</b>	Yes	Same
<b>Blade / window material</b>	Stainless Steel	Same
<b>Shaft Outer Diameter</b>	3.5 mm (RAD 12 & 40 blades)	3.5 mm
<b>Shaft Length</b>	11 cm (RAD 12 & 40 blades)	12 cm
<b>Angle of Distal Tip</b>	12° - 40° (RAD 12 & 40 blades)	0° - 45°
<b>User Interface</b>	Activation switch (footswitch)	Activation switch (hand-piece trigger)
<b>Human Factors</b>	User holds the hand-piece to insert and position device at intended surgical site	Same
<b>Contraindications</b>	None	Same
<b>Method of Introduction</b>	Manual placement under endoscopic guidance	Same
<b>Function</b>	Device is positioned at intended site and switch activated to begin resection.	Same

The technological characteristics and principals of operation of the Laurimed PolypVac Microdebrider are substantially equivalent to the noted predicate device.

**J. Summary of Non-Clinical Data**

The Laurimed PolypVac Microdebrider performance characteristics were evaluated in the following *in-vitro* bench studies:

- Dimensional Verification Testing
- Tensile Testing
- Flow Rate Testing
- Device Durability
- Shaft Malleability and Durability
- Bench Top Performance\*
- Leakage & Syringe Compatibility
- Cadaver Predicate Comparison\*\*
- Biocompatibility Testing
  - Cytotoxicity
  - Sensitization
  - Irritation
- Sterilization Validation
- Packaging Validation
- Shelf Life

**\*Bench-top Performance Testing**

Bench Top Performance Testing using the PolypVac Microdebrider and the Xomed XPS 3000 with RAD40 blades was completed to compare the aspiration rate performance of the subject and predicate device using simulated polyp tissue models. Non-inferiority was demonstrated based on resection rates in two sample tissue models. Data collected on clogging trended in favor of the PolypVac Microdebrider, where the device clogged less frequently than the Xomed XPS 3000 blades. Therefore, the results of this testing demonstrate that the PolypVac Microdebrider is substantially equivalent to the Xomed predicate in terms of aspiration rates in simulated polyp tissue models representing the spectrum of human polypoid tissue.

**\*\*Cadaver Predicate Comparison Testing**

Cadaver Predicate Comparison testing using the PolypVac Microdebrider and the Xomed XPS 3000 with RAD12 and RAD40 blades was completed to compare the performance when used by three (3) independent board-certified ENT surgeons to excise simulated attached sinonasal polyps from worst-case accessible locations in a cadaver model. Non-inferiority was demonstrated based on the degree of complete polyp removal (as measured by grams of unresected tissue). Post-resection images of the attachment site were graded by a blinded reviewer and found to be similar for the PolypVac Microdebrider (average: 1.08) and Xomed XPS 3000 (average: 1.00). Therefore, the results of this testing demonstrate that the PolypVac Microdebrider is substantially equivalent to the Xomed predicate when used to navigate to and resect worst-case polyps during simulated polypectomy procedures in a cadaver model.

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Results of the non-clinical testing demonstrate that the materials chosen, the manufacturing process, and design of the Laurimed PolypVac Microdebrider meet the established specifications necessary for consistent performance during its intended use. This testing demonstrates the Laurimed PolypVac Microdebrider is safe and is substantially equivalent to the named predicate.

**K. Summary of Data**

The Laurimed PolypVac Microdebrider has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing, including comparative testing, was conducted to validate the performance of the device and ensure the Laurimed PolypVac Microdebrider functions as intended and meets design specifications. The comparison and non-clinical performance testing results demonstrate that the Laurimed PolypVac Microdebrider is substantially equivalent to the predicate device for its intended use and does not raise new issues of safety or effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

December 23, 2013

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Laurimed, LLC  
% Ms. Nancy Lincé, RAC  
Lincé Consulting  
8 Crow Canyon Court, Suite 205  
San Ramon, CA 94583

Re: K133133

Trade/Device Name: PolypVac Microdebrider  
Regulation Number: 21 CFR 874.4250  
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill  
Regulatory Class: Class II  
Product Code: ERL  
Received: September 27, 2013  
Dated: September 30, 2013

Dear Ms. Lincé:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tina Kiang -S

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for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

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**Indications for Use Statement**

**510(k) Number (if known):** K 133133

**Device Name:** PolypVac Microdebrider

**Indications for Use:**

Indicated for the excision of polyps in the nasal passageways and in sinuses for which access has been previously established.

**Prescription Use**   X   **Or** **Over-The-Counter Use**             
(per 21 CFR 801.109)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Sageev George -S**  
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